UNITED STATES PATENT AND TRADEMARK OFFICE

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10/551,148	09/29/2005	Atsushi Ogiwara	1254-0294PUS1	4166

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EXAMINER
HURST, JONATHAN M

ART UNIT	PAPER NUMBER
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NOTIFICATION DATE	DELIVERY MODE
10/14/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

PTOL-90A (Rev. 04/07)

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL**.   2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1,3-8,10-12,14-19,21 and 22* is/are pending in the application.

   4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1,3-8,10-12,14-19,21 and 22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *29 September 2005* is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a) ☒ All   b) ☐ Some *   c) ☐ None of:

   1. ☐ Certified copies of the priority documents have been received.

   2. ☐ Certified copies of the priority documents have been received in Application No. _____.

   3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

   * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
   Paper No(s)/Mail Date *9/3/2009*.

4) ☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____ .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

2.   The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.   Determining the scope and contents of the prior art.
2.   Ascertaining the differences between the prior art and the claims at issue.
3.   Resolving the level of ordinary skill in the pertinent art.
4.   Considering objective evidence present in the application indicating
        obviousness or nonobviousness.

3.   Claims 1, 3-8, 11-12, 14-19, and 22 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Norton (US 6,989,100) in view of Klee et al. (US 6,493,639)

        Regarding claim 1 Norton discloses a sample analyzing method, which

comprises:

        (a) Using multiple samples which contain at least one material which may be

used as a reference; (See Col. 4 Lines 35-50, Col. 7 Lines 45-62 and Col. 8 Lines 23-33

where corresponding peaks are used as reference materials).

Norton also discloses a step of (b) obtaining three-dimensional data as a result of chromatography mass spectrometry for the multiple samples, wherein the three-dimensional data comprises a parameter indicating a mass-to-charge ratio, a parameter indicating ionic intensity, and a parameter indicating a retention time; (See Col. 1 Lines 40-43 where data comprises said parameters and said data is reported and therefor must be obtained).

Norton further discloses the steps of (c) correcting the parameter indicating a retention time in the three-dimensional data for the multiple samples using at least one peak of the at least one reference material; (d) comparing the corrected data obtained in said step (c) for the multiple samples to analyze differences among the multiple samples; and (e) outputting a result of the comparison in step (d). (See Col. 1 Lines 15-21, Col. 2 Line 57- Col. 3 Line 5, Col. 7 Lines 45-62, Fig. 4A, and Fig. 8B where in samples comprising multidimensional data retention time is corrected through time-aligning of selected reference peaks and the corrected data is compared among samples and output).

Norton does not specifically disclose the reference materials being added to each of the samples.

Klee et al. discloses a method of analyzing a sample wherein data is obtained from multiple samples and a retention time parameter from said data is corrected by adding internal standards, i.e. reference material, to each sample in order to facilitate

said correction of a retention time parameter. (See Col. 1 Lines 50-67 where internal

standards are added to each sample in order for each sample to have a reference

peak.)

It would have been obvious to one of ordinary skill in the art at the time of

invention to add at least one reference material to each of multiple samples as

described by Klee et al. in the method of Norton et al. because it is well known in the art

that internal standards, i.e. reference materials, can be added to each of multiple

samples in order to provide corresponding reference peaks and facilitate the correction

of retention time in data as is required by Norton.

Regarding claim 3 modified Norton discloses all the claim limitations as set forth

above as well as the sample analyzing method wherein, in said step (c), profiles

regarding parameters, from which a parameter as a correction target has been

excluded, are used as reference profiles, and wherein using an evaluation function

acting as a scale of position similarity regarding a plurality of reference profiles among

multiple samples, the position of each profile is determined as a problem of finding an

optimum solution which optimizes the value of said evaluation function. (See Col. 6

Lines 17-53 where profiles are data sets and data sets not being corrected are

reference data sets and multiple sample data sets are compared to reference data sets

based on similarity using a function and an optimum solution is found based on said

function).

Regarding claim 4 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein said evaluation function is defined with a term regarding similarity and/or distance among profiles regarding a parameter of a correction target. (See Col. 6 Lines 30-53 where the function (2) contains a term regarding the distance among data sets)

Regarding claim 5 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein, in said step (c), a dynamic programming algorithm is used, when the value of said evaluation function is optimized as a problem of finding an optimum solution regarding said parameter of a correction target. (See Col. 6 Lines 53-60 where a dynamic program is used to find an optimum solution to a function to correct a parameter of a target sample)

Regarding claim 6 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein, in said dynamic programming algorithm, when the optimal correspondence of data points contained in a parameter of a correction target is evaluated by calculating scores, the score of a correspondence regarding data points derived from a reference material is set by a point-addition scoring system. (See Col 6 Lines 17-60 where a dynamic program is used to find an optimal solution to function (2) by using a score, which is a distance, calculated by adding terms)

Regarding claim 7 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein, in said dynamic programming algorithm, when the optimal correspondence of data points contained in a parameter of a correction target is evaluated by calculating scores, a constraint condition is set, in which a correspondence regarding data points derived from a reference material is necessarily corresponded at a designated point. (See Col. 8 Lines 16-33 where a constraint regarding data analyzed is set so the data must correspond to each other in at least one point or peak.)

Regarding claim 8 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein said sample comprises a protein group and/or a peptide group. (See Example 1 where human serum comprises proteins)

Regarding claim 11 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing method wherein said at least one reference material is added to said multiple samples in a state where it is immobilized in gel. (See Col. 3 Lines 50-55 where sample is added in gel form and as such the reference material which is included in the sample is in gel form)

Regarding claim 12 Norton et al discloses a computer-readable medium on which is embodied a sample analyzing program comprising instructions which, when

executed, cause a computer to execute: (See Col. 12 Lines 18-44 where a computer

readable medium with program code embodied thereon causes a computer, to execute

methods of the invention.)

A procedure (a) of inputting three-dimensional data obtained as a result of

chromatography mass spectrometry for multiple samples each of which has at least one

reference material, wherein the three-dimensional data comprises a parameter

indicating a mass-to-charge ratio, a parameter indicating ionic intensity, and a

parameter indicating a retention time; (See Col. 4 Lines 35-50, Col. 7 Lines 45-62 and

Col. 8 Lines 23-33 where corresponding peaks are used a reference materials Col. 1

Lines 40-43 where data comprises said parameters Col. 4 Lines 4-10 where data is

input into a computer as a result of the use of an analytical instrument.)

Norton further discloses the computer readable medium causing a computer

executing a procedure (b) of correcting the parameter indicating a retention time in the

three-dimensional data for the multiple samples using at least one peak of the reference

material; a procedure (c) of comparing the data corrected in said procedure (b) for the

multiple samples to analyze differences among the multiple samples; and a procedure

(d) of outputting a result of the comparison in said procedure (c). (See Col. 1 Lines 15-

21, Col. 2 Line 57- Col. 3 Line 5, Col. 7 Lines 45-62, Fig. 4A, and Fig. 8B where in

samples comprising multidimensional data retention time is corrected through time-

aligning of selected reference peaks and the corrected data is compared among

samples and output)

Furthermore it is noted that the computer program as described by Norton is designed to analyze samples comprising any number of compositions and is fully capable of analyzing samples which have reference materials added thereto and correcting said retention time data by using peaks of said reference materials. (See Col. 7 Lines 45-61 and Col. 8 Lines 24-36 where peaks for correcting retention time are chosen manually or by an algorithm and said algorithm is fully capable of choosing reference material peaks if conditions for doing so are met.)

It is noted that a recitation directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art, if the prior art has the capability to so perform. The recitation of a new intended use for an old product does not make a claim to that old product patentable. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Norton does not specifically disclose the reference material being added to each of the samples.

Klee et al. discloses a sample analysis procedure wherein data is obtained from multiple samples and a retention time parameter from said data is corrected by adding internal standards, i.e. reference material, to each sample in order to facilitate said correction of a retention time parameter. (See Col. 1 Lines 50-67 where internal standards are added to each sample in order for each sample to have a reference peak.).

It would have been obvious to one of ordinary skill in the art at the time of invention to have instructions for performing a procedure wherein at least one reference material is added to each of multiple samples as described by Klee et al. in the computer readable medium comprising instructions causing a computer to execute a procedure as described by Norton et al. because it is well known in the art that internal standards, i.e. reference materials, can be added to each of multiple samples in order to provide corresponding reference peaks and facilitate the correction of retention time in data as is required by Norton.

Regarding claim 14 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein, in said procedure (b), profiles regarding parameters, from which a parameter as a correction target has been excluded, are used as reference profiles, and wherein using an evaluation function acting as a scale of position similarity regarding a plurality of reference profiles among multiple samples, the position of each profile is determined by optimizing the value of said evaluation function as a problem of finding an optimum solution.
(See Col. 6 Lines 17-53 where profiles are data sets and data sets not being corrected are reference data sets and multiple sample data sets are compared to reference data sets based on similarity using a function and an optimum solution is found based on said function)

Regarding claim 15 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein said evaluation function is defined with a term regarding similarity and/or distance among profiles regarding a parameter of a correction target; (See Col. 6 Lines 30-53 where the function (2) contains a term regarding the distance among data sets)

Regarding claim 16 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein, in said procedure (a), dynamic programming algorithm is used, when the value of said evaluation function is optimized as a problem of finding an optimum solution regarding said parameter of a correction target. (See Col. 6 Lines 53-60 where a dynamic program is used to find an optimum solution to a function to correct a parameter of a target sample)

Regarding claim 17 modified Norton discloses all the claim limitations as set forth above as well as the sample analyzing program wherein, in said dynamic programming algorithm, when the optimal correspondence of data points contained in a parameter of a correction target is evaluated by calculating scores, the score of a correspondence regarding data points derived from a reference material is set by a point-addition scoring system. (See Col 6 Lines 17-60 where a dynamic program is used to find an optimal solution to function (2) by using a score, which is a distance, calculated by adding terms)

Regarding claim 18 modified Norton discloses all the claim limitations as set forth

above as well as the sample analyzing program wherein in said dynamic programming

algorithm, when the optimal correspondence of data points contained in a parameter of

a correction target is evaluated by calculating scores, a constraint condition is set, in

which a correspondence regarding data points derived from a reference material is

necessarily corresponded at a designated point. (See Col. 8 Lines 16-33 where a

constraint regarding data analyzed is set so the data must correspond to each other in

at least one point or peak.)

Regarding claim 19 modified Norton discloses all the claim limitations as set forth

above as well as the he sample analyzing program wherein said sample comprises a

protein group and/or a peptide group, and wherein multi-dimensional data derived from

said protein group and/or peptide group are analyzed. (See Example 1 where a sample

comprises human serum which comprises proteins and data is obtained from said

sample and analyzed)

Regarding claim 22 modified Norton discloses all the claim limitations as set forth

above as well as the sample analyzing program wherein said reference material is

added to said sample in a state where it is immobilized in gel. (See Col. 3 Lines 50-55

where sample is added in gel form and Col. 4 Lines 36-50 where reference material is a

sample)

4.   Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Norton (US 6,989,100) in view of Klee et al. (US 6,493,639) as applied to claims 1,

3-8, 11-12, 14-19, and 22 above, and further in view of Teschemacher et al. (US

4,681,871)

        Regarding claim 10 Norton discloses all the claim limitations as set forth above

but does not specifically disclose the sample analyzing method wherein said reference

material is at least one type of peptide selected from the group consisting of peptide T

(Ala-Ser Thr-Thr-Asn-Tyr-Thr), beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile), and

a structural analog thereof.

        Teschemacher et al. discloses a sample analyzing method wherein a sample is

analyzed based on the use of liquid chromatography and wherein the sample contains

beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile). (See Example 1 where beta-

casomorphin-7 is isolated as a result of liquid chromatography)

        It would have been obvious to one of ordinary skill in the art at the time of

invention to use beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile) as disclosed by

Teschemacher as the reference material in the sample analyzing method of Norton

because beta-casomorphin-7 fulfills the need for a specific biological sample to be

analyzed which is compatible with chromatographic instruments and can be used as a

reference material (See Norton Col. 3 Lines 50-66 and Col. 4 Lines 36-50) and is known

to be analyzed using chromatographic methods.

Regarding claim 21 Norton discloses all the claim limitations as set forth above

but does not specifically disclose the sample analyzing program wherein said reference

material is at least one type of peptide selected from the group consisting of peptide T

(Ala-Ser-Thr-Thr-Asn-Tyr-Thr), beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile), and

a structural analog thereof.

Teschemacher et al. discloses a sample analyzing method wherein a sample is

analyzed based on the use of liquid chromatography and wherein the sample contains

beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile). (See Example 1 where beta-

casomorphin-7 is isolated as a result of liquid chromatography)

It would have been obvious to one of ordinary skill in the art at the time of

invention to use beta-casomorphin-7 (Tyr-Pro-Phe-Pro-Gly-Pro-Ile) as disclosed by

Teschemacher as the reference material in the sample analyzing program of Norton

because beta-casomorphin-7 fulfills the need for a specific biological sample to be

analyzed which is compatible with chromatographic instruments and can be used as a

reference material (See Norton Col. 3 Lines 50-66 and Col. 4 Lines 36-50) and is known

to be analyzed using chromatographic methods.

Response to Arguments

5.   Applicant's arguments with respect to claims 1-9, 11, 12, 14-20, and 22 have

been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6.   Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

7.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to JONATHAN M. HURST whose telephone number is

(571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00;

Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./

Examiner, Art Unit 1797

/Michael A Marcheschi/
Supervisory Patent Examiner, Art Unit 1797